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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/290,798	04/13/1999	INGEGERG HELLSTROM	9632-033	1277

7590 12/31/2003

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New York, NY 10036-2711

EXAMINER
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YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

28

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/290,798

Applicant(s)

HELLSTROM ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 101-106, 109-116 and 119-128 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 101-106, 109-116 and 120-128 is/are rejected.
- 7) ☒ Claim(s) 119 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 27.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 29.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1642

### **DETAILED ACTION**

1. The amendment filed 10/16/2003 (paper no. 26) is acknowledged and entered into the record. Accordingly, claims 1-100, 107, 108, 117, and 118 are canceled without prejudice or disclaimer, claims 119-128 are newly added.
2. Claims 101-106, 109-116, and 119-128 are pending and examined on the merits.

### ***Information Disclosure Statement***

3. The Information Disclosure Statement filed 10/26/2003 (paper no. 27) is acknowledged and considered. A signed copy of the IDS is attached hereto.

### ***Double Patenting Maintained***

4. The rejection of claims 101-106, 109, 112-116, and now newly added claims 120-128 as being obvious over US Patent 5,980,896 is maintained for the reasons of record. Applicant request that the Double Patenting rejection be held in abeyance until allowable subject matter is found, upon which a Terminal Disclaimer will be filed.

### ***Claim Rejections Maintained - 35 USC § 103***

5. The rejection of claims 101-106, 109-116, and 120-128 under 35 USC 103(a) as being obvious over Abe *et al* in view of Oldham is maintained for the reasons of record. Applicant argues that the instantly claimed invention is drawn to an immunoconjugate that is able to competitively inhibit the binding of the deposited BR96 antibody, which is a Lewis Y antigen specific antibody. Applicant further argues that the AH6 antibody

Art Unit: 1642

disclosed by Abe *et al* is not capable of competing with the BR96 antibody because the epitopes recognized by the two antibodies are different and distinct. Furthermore, applicant argues that the Lewis Y antigen recognized by the BR96 antibody is an extended form of Lewis Y antigen. Applicant's arguments have been carefully considered but are not found persuasive. The antibody taught by Abe *et al* is capable of recognizing the Lewis Y antigen on carcinoma cells (see abstract). Moreover, it is well known and characterized in the art that the extended form of Lewis Y antigen is a multi-fucosylated form of Lewis Y antigen (as evidenced by Kim *et al* Cancer Res 1986 Nov; 46:5985-5992). Furthermore, the specification of the instant invention teaches that BR96 recognizes a variant form of Lewis (Fuc  $\alpha$  1-2Gal  $\beta$  1-4 (fuc  $\alpha$  1-3)GlcNac) antigen with the antigenic portion being comprised of Fuc $\alpha$ 1-3 (see page 116). Abe *et al* discloses an antibody that recognizes Lewis (Fuc  $\alpha$  1-2Gal  $\beta$  1-4 (fuc  $\alpha$  1-3)GlcNac) antigen and because the antigens appear to be similar, it would thereby compete for binding with the BR96 antibody. Therefore, one of skill in the art would have found it obvious at the time the invention was made to use the antibody taught by Abe *et al* because the antibody recognizes the same Lewis Y antigen, and one of skill in the art would have found it obvious to make immunoconjugates with this antibody in view of the teachings of Oldham. The antibody taught by Abe *et al* does not teach the conjugation of the antibody to drugs per se, but these deficiencies are made up by Oldham who does in fact teach the use of immunocojugates in the treatment of cancers. One of skill in the art would have been motivated to combine these references because the antibody taught by Abe *et al* was already taught to be specific for carcinoma cells, and

Art Unit: 1642

the conjugation this antibody to therapeutic moieties is an obvious variation and modification to the antibody.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 26.**

***Conclusion***

6. Claims 101-106, 109-116, and 120-128 are rejected.
7. Claim 119 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1642

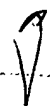
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
December 28, 2003

  
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